

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

In re. PHARMACEUTICAL INDUSTRY	)	MDL No. 1456
AVERAGE WHOLESALE PRICE	)	Civil Action No. 01-12257-PBS
LITIGATION	)	
	)	Hon. Patti Saris
THIS DOCUMENT RELATES TO THE	)	
AMENDED MASTER CONSOLIDATED	)	
CLASS ACTION	)	
	)	

**OPPOSITION OF UNITED STATES TO TRACK ONE DEFENDANTS’  
EMERGENCY MOTION TO DECLARE THE TOUHY REGULATION  
INAPPLICABLE AND FOR LEAVE TO TAKE TRIAL DEPOSITIONS OF  
CERTAIN FORMER GOVERNMENT EMPLOYEES**

**INTRODUCTION**

The United States of America, on behalf of itself and the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS), *amicus curiae*, through its undersigned counsel, hereby opposes the Track One Defendants’ Emergency Motion to Declare the Touhy Regulation Inapplicable and for Leave to Take Trial Depositions of Certain Former Government Employees. By electronic Order dated October 20, 2006, the Court denied the defendants’ request for leave to take trial depositions of the former government employees. Accordingly, the United States does not address that aspect of the defendants’ motion. With respect to the remainder of the defendants’ motion, the motion is meaningless as to former HHS and White House employee Christopher Jennings; and, as to the other former government employees, the defendants’ assertion that the United States is a “party” to the claims being tried in

November is wrong, there is no jurisdictional basis for the Court to entertain the defendants' challenge to CMS' denial of their *Touhy* request, and their challenge is, in any event, without merit.

## **ARGUMENT**

### **A. The Defendants' Motion Should Be Denied As to Former HHS and White House Employee Christopher Jennings**

The Track One defendants seek declaratory relief with respect to Christopher Jennings, a former HHS and White House official. Apparently unaware that for part of the time Mr. Jennings worked at the White House, he was actually employed by HHS, the defendants made their *Touhy* request for Mr. Jennings' testimony by letter dated October 17, 2006, to the White House Office of Administration. Exhibit A, attached.<sup>1</sup> The defendants' letter invoked the *Touhy* regulations at 5 C.F.R. §§ 2502.30, *et seq.* By letter dated October 25, 2006 (Exhibit B attached), the Office of Administration advised counsel for the defendants that the regulations at 5 C.F.R. §§ 2502.30, *et seq.* pertain only to "an employee or former employee of the Office of Administration," and that because Mr. Jennings was not an employee of the Office of Administration, the Office of Administration was not in a position to act on the defendants' request.<sup>2</sup>

---

<sup>1</sup> The letter was not received until October 23, 2006.

<sup>2</sup> Also, the application of the Office of Administration's *Touhy* regulation does depend on whether the United States is a "party" to an action. 5 U.S.C. §§ 2502.30, 2502.31.

On October 31, 2006, HHS confirmed that Mr. Jennings was employed by HHS from February 1993 until November 1994. Defendants have not made any request to HHS for testimony pursuant to the HHS *Touhy* regulations. Thus, there has been no final agency decision regarding his testimony. In sum, there is no *Touhy* issue before this Court as to Mr. Jennings under either set of regulations. The defendants' request to the Office of Administration was misapplied; the Office of Administration's decision declining to act is clearly correct; and defendants have not yet made a request to HHS for testimony by Mr. Jennings.<sup>3</sup>

**B. HHS Is Not a "Party" to the Track One Class Action Cases Scheduled For Trial In November 2006**

With regard to the former HHS employees Thomas A. Scully, Nancy-Ann Min DeParle, and Stanley Weintraub, the defendants' position also lacks substance. As counsel for the United States has previously advised the defendants,<sup>4</sup> the contention that the United States is a "party" to the cases scheduled for trial in November lacks merit.

---

<sup>3</sup> Much like the other former CMS employees from whom defendants have sought testimony, any testimony from Mr. Jennings, as a former senior health care policy adviser, would likely intrude on areas of governmental privilege.

<sup>4</sup> See Exhibit 4 to Declaration of Adam Wright (Docket #3241). The defendants correctly observe that the relevant HHS regulation does not apply where the United States is a party. 45 C.F.R. § 2.1(d)(1). It should be noted that *Touhy* regulations differ from agency to agency, and not all agency regulations are so limited. *E.g.*, 28 C.F.R. § 16.23 (DOJ regulation); 21 C.F.R. § 20.1 (FDA regulation). This Court need not address whether an agency may validly apply its *Touhy* regulation in a case to which the United States is a party.

The defendants sow confusion by asserting that the United States “is a party to MDL No. 1456.” Defendants’ Memorandum at 6 (heading A). But “MDL No. 1456” is not a civil action in its own right; it is simply a designation given to the consolidated proceedings. “[C]onsolidation is permitted as a matter of convenience and economy in administration, but does not merge the suits into a single cause, or change the rights of the parties, or make those who are parties in one suit parties in another.” *Johnson v. Manhattan Ry. Co.*, 289 U.S. 479, 496-97 (1933); *see Albert v. Maine Cent. RR. Co.*, 898 F.2d 5, 7 (1st Cir. 1990) (consolidated cases remain “separate entities” even though consolidated for pretrial purposes); *Fed. Deposit Ins. Corp. v. Caledonia Inv. Corp.*, 862 F.2d 378, 381 (1st Cir. 1988) (“where cases are consolidated for purposes of convenience and judicial efficiency, they retain their separate identity and judgments rendered in each individual action are appealable as final judgments”), *citing In re Mass. Helicopter Airlines, Inc.*, 469 F.2d 439, 441-442 (1st Cir. 1972).<sup>5</sup> Accordingly, the proper inquiry here is whether the United States is a party to the class action claims going to trial in November. Plainly, the United States is not a party to those cases. The United States is not a member of Classes One or Two; it has no pecuniary or other direct interest in the class claims; it does not assert claims under Mass. Gen. Laws ch. 93A; and it has not participated in any of the discovery or pretrial proceedings.

---

<sup>5</sup> Compare *Bay State HMO Mgmt, Inc. v. Tingley Sys., Inc.*, 181 F.3d 174 (1st Cir. 1999) (applying *res judicata* where cases were ordered consolidated into “one proceeding”).

There is no substance to the Track One defendants' contention that the United States' participation in the MDL case is sufficient to make it a *de facto* party. The defendants rely on three factors, none of which has any significance. First, they rely on the United States' participation as an *amicus*. But the law is crystal clear that *amicus* participation does not make one a "party." *National Fuel Gas Distribution Corp. v. TGX Corp.*, 950 F.2d 829, 838-839 (2nd Cir. 1991); *Kerr-McGee Chem. Corp. v. Hartigan*, 816 F.2d 1177, 1181 (7th Cir. 1987); *Adams v. Bell*, 711 F.2d 161, 197 n. 128 (D.C. Cir. 1983). Second, they point to the United States' Motion to Be Added As An Interested Party (Dkt #2909, copy attached as Exhibit C) as evidence of the United States' party status. But the sole purpose of that motion was "to facilitate electronic filings" by the United States of certain papers requested by the Court. *Id.*<sup>6</sup> It implies nothing about the substantive status of the government in these proceedings.

Third, the defendants rely on the transfer of the *qui tam* case *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc.*, Civil Action No. 06-

---

<sup>6</sup> At the time that motion was filed, the United States was preparing its response to the Court's inquiry regarding the possible use of a mass mailing by CMS to Medicare beneficiaries, in connection with notice to class members. *Id.* At that time, the *qui tam* suit by the United States and the relator Ven-A-Care of the Florida Keys, Inc. against Abbott Laboratories, Inc. (Civil Action No. 06-11337-PBS) had not been consolidated as part of MDL No. 1456, and the United States was unable to utilize the court's ECF system without a misleading association with a party to the case. Counsel for the United States inquired of the Court's docket clerk how the United States could electronically file papers without associating itself with any particular party, and the docket clerk responded that the appropriate way to do this was to file a motion to be added as an "interested party."

11337-PBS, to the MDL for consolidation. But, as the cases cited above establish, the consolidation of the *qui tam* suit against Abbott into the MDL proceedings does not make the United States a “party” to any of the other cases in the MDL. *See Johnson v. Manhattan Ry. Co.*, *supra*, and other cases cited above.

The cases relied upon by the defendants, *Southmark Properties v. Charles House Corp.*, 742 F.2d 862 (5th Cir. 1984), and *Treasure Salvors, Inc. v. Unidentified Wrecked and Abandoned Sailing Vessel*, 459 F. Supp. 507 (D. Fla. 1978), are wide of the mark. They address whether there was sufficient identity of parties to support a finding of *res judicata*. Even assuming that principles of *res judicata* are relevant here, these cases are wholly inapposite. In *Southmark*, the court held that the president of a development company was bound by a prior bankruptcy judgment against the company, notwithstanding that the president himself was not named as a party to the earlier proceeding. The court held that there was sufficient identity between the president and his company because (1) he was its president and a major stockholder, (2) he was a guarantor on the construction loan at issue in the two proceedings, (3) he had a direct pecuniary interest in the outcome of the prior proceeding, and (4) he had exercised substantial control over the prior litigation on behalf of the company. 742 F.2d at 870. Obviously, the United States’ position here bears no resemblance to the facts in *Southmark*. The United States has no relationship to any of the class action plaintiffs, it has no pecuniary interest in the outcome of the class actions, and it has exercised no control whatsoever over the class action litigation.

*Treasure Salvors* was an *in rem* action to determine interests in a maritime vessel – a type of action intended to resolve all ownership disputes, and the district court held that the State of Florida was bound by an earlier judgment in the case entered prior to the State’s involvement. The *in rem* nature of the case places it in a different category; in such cases, the law places an obligation on plaintiffs with adverse interests to intervene. *See Bankers Trust Co. v. Old Republic Ins. Co.*, 697 F. Supp. 1483, 1487 (N.D. Ill. 1988). Furthermore, on appeal, the Court of Appeals for the Fifth Circuit characterized the trial judge’s *res judicata* analysis as “innovative” and declined to either affirm or reverse it. 721 F.2d 1340, 1344 n.17 (1980), *aff’d in part and rev’d in part*, *Florida Dept of State v. Treasure Salvors, Inc.*, 458 U.S. 60 (1982).

Much more to the point is First Circuit precedent (which defendants fail to cite) that belies the defendants’ position. In this Circuit, the most relevant test in determining whether a nonparty should be treated as a *de facto* party is whether the nonparty either “participated vicariously in the original litigation by exercising control over a named party or had the opportunity to exert such control.” *Gonzalez v. Banco Central Corp.*, 27 F.3d 751, 758 (1st Cir. 1994); *see also Perez-Guzman v. Gracia*, 346 F.3d 229, 236 (1st Cir. 2003; *Tapalian v. Town of Seekonk*, 188 F. Supp. 2d 136, 141 (D. Mass. 2002). “Substantial control means what the phrase implies: . . . the power . . . to call the shots.” *Gonzalez v. Banco Central Corp.*, 27 F.3d at 758.<sup>7</sup> Mere commonality of interests will

---

<sup>7</sup> “The burden of persuasion ultimately rests with him who asserts that control (or the right to exercise it) existed to such a degree as would warrant invoking nonparty

not suffice. *Perez-Guzman v. Gracia*, 346 F.3d at 236. Here, there is no suggestion that the United States has ever exercised, or had the ability to exercise, control over the class action cases now pending before the Court. An illustrative case in which the United States was found to be a *de facto* party is *Montana v. United States*, 440 U.S. 147 (1979). In that case, it was stipulated that the United States government had required its contractor to file the state court suit; reviewed and approved the complaint; paid the attorney fees and costs; directed the appeal from the state district court to the state supreme court; appeared and submitted a brief as *amicus curiae* in the state supreme court; directed that a notice of appeal to the United States Supreme Court be filed; and then effected abandonment of the appeal on advice of the Solicitor General. The facts of the *Montana* case speak for themselves.

**C. The Court Lacks Jurisdiction Over the Defendants' Motion For Declaratory Relief Concerning the Former CMS Employees**

To the extent the defendants challenge the CMS decision to deny the request for testimony of former CMS employees Thomas Scully, Nancy-Ann Min DeParle, and Stanley Weintraub, this Court lacks jurisdiction to consider the issue. A challenge to an agency's decision under its *Touhy* regulation, which triggers the doctrine of sovereign immunity, must be made either as an independent action against the agency under the Administrative Procedure Act, 5 U.S.C. § 702 ("APA"), see *Kwan Fai Mak v. FBI*, 252

---

preclusion." *Tapalian v. Town of Seekonk*, 188 F. Supp. 2d at 141, quoting *Gonzalez v. Banco Central Corp.*, 27 F.3d at 759.



F.3d 1089, 1091 n. 5 (9th Cir. 2001) (“[T]he proper procedure for the party seeking to compel disclosure in such circumstances is to file a separate action in federal court under the APA.”), or in a proceeding to enforce a Rule 45 subpoena. *See United States E.P.A. v. General Electric Co.*, 197 F.3d 592, 597-598 (1999), *modified in part*, 212 F.3d 689 (2d Cir. 2000); *COMSAT Corp. v. Nat’l Sci. Found.*, 190 F.3d 269, 274, 277 (4th Cir. 1999); *and see In re Boeh*, 25 F.3d 761, 764-65 (9th Cir. 1994); *Boron Oil Co. v. Downie*, 873 F.2d 67, 70 (4th Cir. 1989). District courts simply do not have roving jurisdiction to overturn final agency action by way of a motion for a “declaration” in cases to which the United States is not a party. Here, the defendants have not filed an action under the APA, nor have they moved to enforce any subpoena. Indeed, no subpoenas have issued to any of the former employees – no doubt because they are beyond the geographic subpoena authority of Rule 45. *See Fed. R. Civ. P. 45 (b)(2)*.<sup>8</sup> In short, there is no matter properly before the Court that provides a jurisdictional basis for judicial action.

**D. The Agency’s Decision To Deny the Request Is Not Arbitrary or Capricious**

Even if CMS’s decision not to authorize the testimony were reviewable by the Court, such review would be governed by the “arbitrary and capricious” standard of the APA. *E.g., COMSAT Corp. v. Nat’l Sci. Found.*, 190 F.3d at 271 (“[W]hen the government is not a party to the underlying action, an agency’s refusal to comply with a

---

<sup>8</sup> This would include Mr. Jennings, as discussed previously.

subpoena must be reviewed under the standards established for final agency actions by the [APA]”). In their motion, the defendants do not argue that the agency’s decision was arbitrary and capricious. Instead, defendants indirectly challenge the CMS denial of their *Touhy* request, and they do so solely on the ground that a justification for the *Touhy* regulation – the conservation of agency resources – is not present when the request is aimed at former agency employees. But conservation of agency resources is not the only basis on which an agency may deny a request for information. *See, e.g., United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 473 (1951) (J. Frankfurter, concurring)(noting, even though the issue was not before the Court, that “[i]t will of course be open to [the Attorney General] to raise those issues of privilege from testimonial compulsion”); *Exxon Shipping Co. v. United States*, 34 F.3d 774, 776 (9th Cir. 1994) (recognizing that the federal government is “free to raise any possible claims of privilege from testimonial compulsion that may rightly be available to it”). The defendants’ argument is therefore infirm.

Here, CMS has based its decision on other valid grounds. The agency concluded that the information sought is available in documents already provided to the defendants or publicly available. Exhibit 7 to Declaration of Adam Wright (Docket #3241) at 2. CMS further concluded that, to the extent defendants seek testimony about the reasons for and development of the individuals’ views as set forth in congressional testimony and Federal Register publications, such statements are based on discussions with senior policy advisors and counsel, and such testimony would therefore compromise the agency’s

deliberative process and attorney-client privileges. *Id.* at 2-3. In addition, it appears that, contrary to the defendants' protestations, their objective is to have former agency officials testify regarding the meaning of "average wholesale price." The agency correctly observed that the meaning of the terms of a statute or regulation is determined on the basis of the statutory or regulatory language and, if appropriate, the public historical record of the legislation or regulation, not on the basis of testimony by former or present federal regulators. *Id.* at 3; *see United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (reversing district court's interpretation of federal regulation based on affidavits of present and former agency officials, stating "agency interpretations are only relevant if they are reflected in public documents . . . . The non-public or informal understandings of agency officials concerning the meaning of a regulation are thus not relevant."). The defendants have failed to present any basis for overturning any of the CMS determinations as arbitrary and capricious.

## CONCLUSION

For the foregoing reasons, the Court should deny the Track One Defendants' Emergency Motion to Declare the Touhy Regulation Inapplicable and for Leave to Take Trial Depositions of Certain Former Government Employees.

Respectfully submitted,

MICHAEL J. SULLIVAN  
United States Attorney

By: /s/ George B. Henderson, II  
George B. Henderson, II  
Assistant U.S. Attorney  
John J. Moakley U.S. Courthouse  
1 Courthouse Way, Suite 9200  
Boston, MA 02110  
(617) 748-3272

## CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above "Opposition of United States to Track One Defendants' Emergency Motion to Declare the Touhy Regulation Inapplicable and for Leave to Take Trial Depositions of Certain Former Government Employees" to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Dated: October 31, 2006

/s/ George B. Henderson, II  
George B. Henderson, II